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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,790	11/12/2003	Gerald B. Pier	B0801.70255US01	5867

23628 7590 12/18/2006
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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/18/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/713,790

Applicant(s)

PIER ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28, 42, 45, 60, 62, 66, 68, 78 and 82 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 26-28, 45, 60, 62, 66, 68, 78 and 82 ~~is/are~~ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 42 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>92404, 52505, 122705, 31306, 51906</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Preliminary Amendment

- 1) Acknowledgment is made of Applicants' preliminary amendment filed 05/21/04.

Election

- 2) Acknowledgment is made of Applicants' election filed 09/01/06 in response to the restriction requirement mailed 08/01/06. Applicants have elected, with traverse, invention I, claims 1-25 and 42. Applicants' traversal is on the grounds that search and examination of all the groups would not place a serious burden on the Office. Applicants request rejoinder of invention IV should the claims of invention I be found allowable, provided that the claims of invention IV depend from or otherwise include all the limitations of the allowable claims of invention I.

Applicants' arguments have been carefully considered, but are not persuasive. With regard to the rejoinder of claims from invention IV, Applicants should note paragraph 9 of the restriction requirement mailed 08/01/06. With regard to the alleged lack of serious burden, as set forth previously, the claimed polysaccharide is made of saccharide units, whereas the claimed binding agent such as an antibody, is a glycoprotein which includes IgG comprising 2 heavy and 2 light chains containing constant and variable regions, including framework regions that act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. The two products and the methods of using or making each, require at least separate individual structural searches and would impose a serious search burden. For these reasons, the restriction requirement set forth in the instant application is proper and is hereby made FINAL.

Status of Claims

- 3) Claims 1-28, 42, 45, 60, 62, 66, 68, 78 and 82 are pending.

Claims 26-28, 45, 60, 62, 66, 68, 78 and 82 have been withdrawn from consideration as being directed to a non-elected invention or non-elected species. See 37 C.F.R. 1.142(b) and M.P.E.P. § 821.03.

Claims 1-25 and 42 are under examination.

Information Disclosure Statements

- 4) Acknowledgment is made of Applicants' information disclosure statements filed 09/24/04, 05/25/05, 12/27/05, 03/13/06 and 05/19/06. The information referred to therein has been

considered and a signed copy is attached to this Office Action.

Sequence Listing

- 5) Acknowledgment is made of Applicants' CRF and raw sequence listing which have been entered on 12/02/03.

Priority

- 6) The instant application claims priority to the provisional application 60/425,425, filed 11/12/02.

Specification

- 7) The specification to for the following reason(s):

The use of the trademark in the instant specification has been noted. For example, see line 2 on page 42: 'Sephacryl'; line 25 on page 43; and line 18 on page 44: Superose 6'. The recitation should be capitalized wherever they appear. See M.P.E.P 608.01(V) and Appendix I. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification to make similar corrections to trademark recitations, wherever such recitations appear.

Double Patenting

- 8) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

Claims 1-3, 6, 8, 9, 11, 14, 19 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 63 of the co-pending application 10/713,790. Claim 18 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 67 of the co-pending application 10/713,790. Although the conflicting claims are not identical, they are not patentably distinct from each other because the product of claims 63 and 67 of the above-identified co-pending application falls within the scope of the above-identified claims. The portions of the disclosure from the co-pending application that provide support for the isolated PS/A polysaccharide composition having a molecular weight of >100,000 daltons and being greater than 92% pure as claimed, do not exclude, but expressly encompass an isolated sterile beta-1,6-glucosamine polymer composition differing in the degree of acetate substitution (inclusive of less than 50% acetate substitution). See the structures disclosed on pages 3 and 5; and sections [0067] and [0129] of the published version (US 20020119166) of the co-pending application 10/713,790.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

9) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

10) Claims 4, 6, 11, 12, 14, 16, 17, 22-25 and 42 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 4 lacks proper antecedent basis in the limitation 'R groups'. Claim 4 depends from claim 3, which already recites 'the R groups'. For proper antecedent basis, it is suggested that Applicants replace the limitation with --the R groups--.

(b) Analogous rejection and criticism apply to the limitation 'n' in claim 6.

(c) Claim 11 is indefinite in the improper Markush language: 'selected from the group consisting of at least 400 at least 500 monomer units' without the use of the limitation --and- in between the two monomer units. The limitation 'at least 400 at least 500 monomer units' does not make sense.

(d) Claim 12 lacks proper antecedent basis in the limitation 'glucosamine amino groups' (see line 3). Claim 12 depends from claim 1, which already includes the limitation: 'glucosamine amino groups'. For proper antecedent basis, it is suggested that Applicants replace the limitation in claim 12 with --the glucosamine amino groups--.

(e) Claim 42 is vague in the limitation: 'an effective amount to stimulate an immune response' without particularly reciting or pointing out in whom the immune response is stimulated.

(f) Claim 14 is vague and/or confusing in the limitation: 'the composition has a purity selected from the group consisting of at least 90% pure, at least 95% pure, at least 97% pure, and at least 99% pure. Is it the composition that has the recited percent purity, or is it the isolated polysaccharide comprised in the claimed composition that has the recited percent purity?

(g) Claims 16 and 17 have improper antecedent basis in the limitation: 'the carrier compound'. Claims 16 and 17 depend from claim 1, which does not recite 'a carrier compound'.

(h) Claim 22 is indefinite and/or appears to lack proper antecedent basis in the limitation: 'only one carrier compound or linker joined to a carrier compound is conjugated'. Claim 22 depends from claim 21, which already recites 'a carrier compound' and 'a linker joined to a carrier compound'. Does it mean that the 'only one carrier compound or linker joined to a carrier compound' recited in claim 22 is different from the one recited in the base claim 21?

(i) Claim 23 is indefinite and/or appears to lack proper antecedent basis in the limitation: 'only one of X1, X2, X3, X4, X5 or X6 ... conjugated to a carrier compound or linker joined to a carrier compound'. Claim 23 depends directly from claim 22 and indirectly from claim 21. Claim 21 already recites X1, X2, X3, X4, X5 or X6; a carrier compound; and a linker joined to a carrier compound. Does it mean that the 'only one of X1, X2, X3, X4, X5 or X6 ... conjugated to a carrier compound or linker joined to a carrier compound' recited in claim 23 is different from the one recited in the base claim 21?

(j) Claim 24 is indefinite and/or appears to lack proper antecedent basis in the limitation: 'only one of Y1, Y2, or Y3 conjugated to a carrier compound'. Claim 24 depends from claim 21. Claim 21 already recites Y1, Y2 or Y3. Does it mean that the 'only one of Y1, Y2, or Y3 ... conjugated to a carrier compound' recited in claim 24 is different from the one recited in the base claim 21?

(k) Claim 24 is indefinite, confusing, and/or incorrect in the limitation: 'conjugated to a carrier compound linker conjugate to a carrier compound'. The phrase makes no sense. The scope of the claim is not clear.

(l) Claim 25, which depends from claim 22, is also rejected as being indefinite because of the indefiniteness identified above in claim 22.

Rejection(s) under 35 U.S.C § 102

11) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless—

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12) Claims 1-16 and 18-24 are rejected under 35 U.S.C § 102(b) as being anticipated by McKenney *et al.* (*Infect. Immun.* 66: 4711-4720, October 1998 - Applicants' IDS).

McKenney *et al.* taught a composition comprising or consisting of an isolated and purified large molecular weight beta-1,6-glucosamine polysaccharide substituted with zero to 33% acetate. The polysaccharide can also be additionally succinate-substituted, i.e., hetero-substituted. The composition further contains phosphate buffered saline and is filter-sterilized. The polysaccharide contained glucosamine as the single sugar component, and therefore is expected to be at least 90% pure. See first full paragraph on page 4714; and paragraph bridging pages 4712 and 4713. The molecular weight of the polysaccharide is >250,000 kDa, and therefore would be expected to contain at least two or four monomeric units of the structure recited in claims 2 and 21, wherein n is at least 6, wherein X1, X2, X3, X4, X5 and X6 is H, and Y1, Y2 and Y3 is OH, wherein one of the X1, X2, X3, X4, X5 or X6, or Y1, Y2 or Y3 in the monomeric units is conjugated to the adjacent saccharide unit(s), i.e., a carrier compound. See abstract.

Claims 1-16 and 18-24 are anticipated by McKenney *et al.*

Rejection(s) under 35 U.S.C § 103

13) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

14) Claim 25 is rejected under 35 U.S.C § 103(a) as being unpatentable over McKenney *et al.* (*Infect. Immun.* 66: 4711-4720, October 1998 - Applicants' IDS) as applied to claims 22 and 21 above, and further in view of Pier *et al.* (US 20020119166 – Applicants' IDS).

The teachings of reference of Pier *et al.* is applied in this rejection because it qualifies as prior art under subsection (e) or (a) of 35 U.S.C. § 102 and accordingly is not disqualified under U.S.C. 103(a).

The teachings of McKenney *et al.* are explained above which do not expressly disclose that the at least four monomeric beta-1,6-glucosamine polysaccharide is conjugated to a carrier compound that is not an N-acetyl beta 1-6 glucosamine.

However, conjugating an isolated staphylococcal poly-beta-1-6-N-acetylglucosamine to a carrier compound including a carrier protein such as BSA or KLH, a peptide, or a lipid using conjugation methods well known in the art was routine and conventional in the art at the time of invention for the purpose of enhancing its immunogenicity in a species of animal to be immunized. For example, see sections [0028], [0085], [0086], and [0089] of Pier *et al.*

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to conjugate McKenney's isolated beta-1,6-glucosamine polysaccharide to an art-known carrier protein such as KLH or BSA using an art-known conjugation technique as taught by Pier *et al.* to produce the instant invention with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of enhancing the immunogenicity of McKenney's isolated beta-1,6-glucosamine polysaccharide in a species of animal to be immunized as taught by Pier *et al.*

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Claim 25 is *prima facie* obvious over the prior art of record.

Remarks

- 15)** Claims 1-25 and 42 stand rejected.
- 16)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted to fax number (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.
- 17)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
- 18)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

November, 2006


S. DEVI, PH.D.
PRIMARY EXAMINER